K082496

SEP 09 2008

510(k) Summary

[As required by section 807.92(c)]

1. Submitter:
   ICP electronics Inc.
   3F, No.22 Chung-Hsing Road, Shi-Chi City, Taipei Hsien 221, Taiwan.

2. Official Correspondent:
   Yvonne Chen (Ms.)

3. Date of 510(k) Submittal: 1. February, 2008

4. Device Trade Name
   PACSmate MMD-3213M monitor

5. Common Name: LCD monitor

6. Classification Name:
   Medical displays were classified in class II (21 CFR 892.2050)

7. Device Product Code:
   LLZ

8. Predicate Device:
   Manufacturer: EIZO NANAO CORPORATION
   Device name: Monochrome LCD monitor
   Model name: RadiForce GS320
   510(k) No.: K062053

9. Device Description:
   The MMD-3213M LCD monitors are displays for medical image viewing. MMD-3213M provides 3 mega pixel resolution.

10. Intended Use:
    The device is intended to be used to as a tool in displaying and viewing digital images view and analyses by trained medical practitioner. The device is not specified for digital mammography system.

11. Technological Characteristics:
    The PACSmate MMD-3213M is a high performance, 3 Megapixel

medical grade monochrome LCD monitors designed for exacting needs for diagnostics professionals that provide clear and sharp images with resolutions of up to 2048 x 1536 pixels, 600 cd/m^2 brightness and 700:1 contrast ratio, making it ideal for diagnosing detailed medical graphics. Also uses a DVI digital interface offering compatibility with the latest digital standards.

12. Performance Testing:

The performance test results for the PACSmate LCD monitor demonstrated that the device meets its intended use specifications and therefore meets the requirements necessary for its intended use as a displayer for medical image.

13. Substantial Equivalence to Predicate Device:

PACSmate MMD-3213M is substantially equivalent to RadiForce GS320. MMD-3123M employs the maximum resolution values same as that of RadiForce GS320. Comparison table of the principal characteristics of two devices is shown in the Section I-2 and specification data for the system monitor is included in Section II.

14. Conclusion:

In terms of intended use, construction, function, safety, operating environmental conditions, and effectiveness of the PACSmate MMD-3213M monitor is substantially equivalent to the predicate device used for this application.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 0 9 2008

IEI Technology Corporation
% Mr. Morten Simon Christensen
Staff Engineer & FDA Accredited Person
Program Coordinator, Program Reviewer
Underwriters Laboratories, Inc.
455 E. Trimble Road
SAN JOSE CA 95131-1230

Re: K082496
Trade/Device Name: PACSmate MMD-3213M Monitor
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: LLZ
Dated: August 18, 2008
Received: August 29, 2008

Dear Mr. Christensen:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometrics' (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Joyce M. Whang, Ph.D.
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K082496

Indications for Use

510(k) Number (if known): Not known

Device Name: PACSmate MMD-3213M monitor

Indications For Use:
The device is intended to be used to as a tool in displaying and viewing digital images view and analyses by trained medical practitioner. The device is not specified for digital mammography system.

Prescription Use __√__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K082496